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| **Prolactin** |
| **Purpose** | This procedure provides instructions for PROLACTIN on the Dimension Vista® System. The PRL method is an *in vitro* diagnostic test for the quantitative measurement of prolactin in human serum and plasma. Measurements are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain. |
| **Policy Statements** | This procedure applies to all Dimension Vista® System operators. |
| **Principle** | The PRL method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-PRL monoclonal antibody fragment. The first bead reagent (Chemibeads) is coated with anti-PRL monoclonal antibody and contains chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. Sample is incubated with biotinylated antibody and Chemibeads to form bead-PRL-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads triggering a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is a direct function of the prolactin concentration in the sample.NOTE: This assay is sensitive to increased supplemental biotin circulating in the blood. Results may be falsely decreased at high levels of supplemented biotin. |
| **Clinical Significance** | Prolactin is a single chain polypeptide hormone secreted by the anterior pituitary. Prolactin initiates and maintains lactation in females and suppresses gonadal function in both sexes. Women are reported to have slightly higher levels than men. Levels rise at puberty and fall at menopause. During pregnancy, the prolactin level climbs steadily to ten or twenty times its former value, then drops back down to normal after delivery — within three weeks in nonnursing mothers. In those who breast-feed, the decline to normal is more gradual because of the prompt and dramatic surges in prolactin release induced by suckling. Women taking oral contraceptives or under estrogen treatment may have prolactin levels higher than normal. Persistent elevations of prolactin are generally caused by disorders of the pituitary. Such disorders can result in a decrease or cessation of menstruation in females and infertility, milk production, and decreased libido in both sexes.Up to 25% of elevated prolactin results may be due to alternate forms of prolactin having little or no biological activity (macroprolactin). In men and older individuals, the tumors are often macroprolactinomas, which may cause hypopituitarism or visual effects. In assessing the significance of moderate elevations, it is important to keep in mind that prolactin is a stress hormone. Not only surgery, but events no more distressing than venipuncture or a clinical interview have been reported to cause a transient rise. The release of prolactin is inherently episodic, and day‑to‑day fluctuations with CVs as high as 30% have been encountered. Finally, there is a sleep-related diurnal variation: prolactin levels increase during sleep and reach their lowest a few hours after waking. The advice sometimes given to draw samples "between nine and noon" is based on the assumption that subjects observe reasonably normal waking hours. |
| **Instrument** | PRIMARY METHOD: Siemens Dimension Vista 500SECONDARY (BACKUP) METHOD: Siemens Dimension Vista 500 on opposite campus  |
| **Sunquest Test Code** | **PROL** Serum Prolactin ng/mL |
| **Specimen** | Lithium heparin plasma, Serum (no gel). Refer to the Specimen Collection Manual for collection of specimens.**Minimum Volume:**200μL preferred, 100μL minimum, 2 μL actual test volume**Stability:*** 7 days at 2 - 8 °C, or 3 months at -20°C.
* Freeze samples only once and mix thoroughly after thawing.
* Thawed frozen specimens which are turbid must be clarified by centrifugation prior to testing
* Serum specimens are stable for up to 24 hours on the clot at room temperature.

**Specimen Rejection:*** Samples and controls stabilized with sodium azide cannot be used
* Unlabeled

 **Preparation:**1. Complete clot formation should take place before centrifugation to prevent the appearance of fibrin in serum samples. Serum or plasma should be physically separated from cells with a maximum limit of 2 hours from the time of collection. Specimens should be free of particulate matter.
2. Whole blood specimens should be centrifuged according to Specimen Processing procedures prior to analysis. See Processing Procedure Manual.
3. Transfer serum or plasma to a properly labeled Siemens SSC nested on a bar-coded pilot tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
4. Very lipemic or frozen samples that become turbid after thawing must be clarified by centrifugation before testing.
5. Patient should not take high doses of biotin within the 24 hours prior to testing.
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| **Reagents** |

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| PRL Flex® reagent cartridge (Vista)*Liquid , ready to use* | K6462 | **Store at:** 2 - 8 °C.**Unopened:** Refer to carton for expiration date of individual unopened reagent cartridges. **On-board:** Sealed wells on the instrument are stable for 30 days.**Open well stability:** 7 days for wells 1 - 12. |
| LOCI 8 CAL (Vista) *Traceable to WHO 3rd IS for PRL 84/500* | KC646 | **Store at:** -25 to -15 °C.**Unopened:** Refer to carton for expiration date.**Preparation:** Thaw and equilibrate at 22 – 28 °C for 1 hour. Mix by inverting 10 times. Do not vortex.**On-board:** Once the vial stopper is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista® System**Opened:** Once the cap is removed, the assigned values are stable for 7 days when recapped immediately and stored at 2 - 8 °C. Do not use this vial on board. |

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| **Special Safety Precautions** | Irritant. Contains a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2Hisothiazol- 3-one (3:1).* May cause sensitization by skin contact.
* Avoid contact with skin.
* Wear suitable gloves.
* Safety data sheets (MSDS/SDS) available on [www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)
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| **Calibration** |

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| Assay Range: | 0.2 – 250 ng/mL |
| Calibration Material: | LOCI 8 CAL, Cat. No. KC646 |
| Calibration Scheme | 5 levels, n = 3 |
| Typical Calibration Levels | Level 1 (Calibrator A): 0 ng/mLLevel 2 (Calibrator B): 20 ng/mLLevel 3 (Calibrator C): 75 ng/mLLevel 4 (Calibrator D): 150 ng/mLLevel 5 (Calibrator E): 275 ng/mL |
| Calibration Frequency: | * Every 30 days
* For each new lot of Flex® reagent cartridges
* After major maintenance or service, if indicated by quality control results
* As indicated in laboratory quality control procedures
* When required by government regulations
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Consult the Vista Calibration Procedure or your Vista iGuide for calibration instructions. |
| **Analytical Measuring Range (AMR)** | Cal Verification and AMR verification meet regulatory requirements with each calibration using 5 calibrators that span the full measuring range. |
| **Quality Control** | Biorad Immunoassay Plus Control, 2 levels. Allow the controls to reach room temperature, and swirl to mix before use. **Frequency:** Two levels once each day of patient testing.**Stability:** Refer to the Biorad product insert **Sunquest Control Names:** Level 1 = C-IMM4, Level 3 = C-IMM6.**Acceptable Ranges:** Ranges are current in Sunquest and the instrument. Refer to the Quality Control Procedure for QC exception codes. |
| **Interferences** | Interferences:At typical prolactin concentrations and biotin concentrations of 1200 ng/mL, results will be decreased up to 31%. No interference was found for:* Commonly used drugs.
* HIL:
	+ Hemoglobin (free) up to 1000 g/dL
	+ Bilirubin (conjugated or unconjugated) up to 60 mg/dL
	+ Lipemia (Intralipid®) up to 3000 mg/dL

Non-Interfering Substances:Refer to the product insert for a list of substances that were shown to have no measurable effect on the PRL result at typical concentrations.**Hook effect**One step sandwich immunoassays are susceptible to a high-dose “hook effect”, where an excess of antigen prevents simultaneous binding of the capture and detection antibodies to a single analyte molecule.The PRL method shows no hook effect up to 50000 ng/mL |
| **Reference Range** |

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| Age | Male | Female |
| 1-7 days | 30-495 ng/ mL | 30-495 ng/mL |
| 1-6 wks | 29-145 ng/ mL | 29-145 ng/mL |
| 6-8wks | 11-23 ng/ mL | 11-23 ng/mL |
| >2 months | 3-18 ng/ mL | 3-24 ng/mL |

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| **Critical Values** | None specified. |
| **Limitations** | Linear range of detection: **0.2 – 250** ng/ mLThe instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in prolactin results. Refer to your Dimension Vista® Operator’s Guide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed prior to reporting.Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution. |
| Dilutions |

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| **Prolactin** |
| Surplus Rack | Samples with results >**250 ng/mL** are repeated on a higher dilution (**1:4**). |
| Limited Rack | Samples with results >**250 ng/mL** should be repeated as an Add-On Test with a Special Dilution of 1:4 |

Refer to your Dimension Vista® Operator’s Guide. |
| **Result Reporting** | * Results between  **0.2 – 250 ng/mL** without error messages are released
* All results will have the following comment appended: “Supplemented Biotin may falsely decrease this assay.  Repeat the testing 24 hours after the last biotin dose."
* Results below 0.2 ng/mL: report as < 0.2 ng/mL instead of the numerical value.
* Results >250 ng/mL without messages are reported following a maximum dilution of 1:4
* Results that exceed the assay range following a maximum dilution of 1:4 are reported as greater than 1,000 ng/mL
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in numbered specimen rack by accession number. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Siemens Dimension Vista® PRL Flex® reagent cartridge Instructions for Use, Siemens Healthcare Diagnostics Inc. Newark, DE 19714, U.S.A., [www.siemens.com/diagnostics](http://www.siemens.com/diagnostics) 2015-03-25 B PN 781462.001 – US
2. Siemens Dimension Vista® LOCI 8 Calibrator Instructions for Use, Siemens Healthcare Diagnostics Inc. Newark, DE 19714, U.S.A., 04/2012, PN 751646.001
3. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th Edition, 2001
4. Burtis CA, Ashwood ER, Bruns, DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed. St Louis, MO: Elsevier Saunders, 2006.
5. Biorad Immunoassay Plus Control Product Insert
6. Siemens Diagnostics Customer Bulletin, 11313747, Rev. A, 2017
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | L. Lichty/C. Bryant | 4/2005 | Replaces Prolactin on ACS180:SE, D. Riedel, 7/2001 |
|  | L. Lichty | 10/2006 | Prolactin on Immulite 2000 |
|  | L. Lichty | June 1, 2011 | New format, updated package insert |
|  | L. Lichty | April 8, 2013 | New maximum dilution, clarify reporting, remove level 2 QC |
|  | L. Lichty | July 22, 2014 | Replaces Prolactin on Immulite 2000. |
|  | Erin Bartos | June 26, 2017 | Updated IFU, Biennial Review |
|  | Erin Bartos | January 8, 2018 | Biotin interference added |
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